UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,266	08/26/2003	Howard R. Levin	JHN-3659-71	2067

23117 7590 07/29/2008

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	
MAIL DATE	**DELIVERY MODE**
07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,266	LEVIN ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 53-60 have been considered but are moot in view of the new ground(s) of rejection. However examiner will address the essence of applicant's arguments. While Prosl does not anticipate the step of inserting a withdrawal needle in a surface peripheral vein near a skin surface of the patient, Prosl does teach that an "AV fistula" which involves inserting a withdrawal needle to connect a patient's major artery to a patient's major vein subcutaneously in the arm is well known as the "gold standard" for vascular access for hemodialysis. (Col. 1, lines 65-67, Col. 2, lines 17-21, Col. 3, lines 48-51) and that the vascular access method of the disclosed invention is an alternative method of vascular access to the AV fistula. Thus, it would be obvious to one of ordinary skill in the art to insert a withdrawal needle in a surface peripheral vein near the skin surface of the patient with a reasonable expectation of success to provide reliable vascular access for a hemodialysis procedure. It is unclear what applicant's remarks regarding the Jaski reference are intended to pertain to since no reference other than the Prosl reference was cited against the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prosl et al ('206).

With respect to **claim 53:** Prosl teaches an extracorporeal method for treating blood from a patient. With initial regard to step a, the method of Prosl discloses the step of inserting a withdrawal needle in a surface peripheral vein, an internal jugular vein near the surface of the chest, in an extremity of the patient. With regard to step b, Prosl discloses the step of applying a suction to the withdrawal needle via suction line 55 to draw blood from the surface peripheral vein through the withdrawal needle. Steps c and d flow inherently and necessarily from the teachings of Prosl since the steps of determination are based upon an arbitrary predetermined threshold amount of blood that the method of Prosl is capable of yielding. With regard to step e, Prosl discloses drawing blood from the reservoir of blood into the withdrawal catheter 22 and into the withdrawal blood tube (suction line 55) of an extracorporeal blood circuit. With regard to step f, Prosl discloses applying a suction pressure to the withdrawal blood tube 55 to cause blood to flow into the blood withdrawal catheter 22. (Figs. 2,3, Col. 2, line 53 – Col. 3, line 9)

With further regard to step a, Prosl does teach that an "AV fistula" which involves inserting a withdrawal needle to connect a patient's major artery to a patient's major vein subcutaneously in the arm is well known as the "gold standard" for vascular access for hemodialysis. (Col. 1, lines 65-67, Col. 2, lines 17-21, Col. 3, lines 48-51) and that the vascular access method of the disclosed invention is an alternative method of vascular access to the AV fistula. Thus, while Prosl does not teach that the surface peripheral vein is near a skin surface of the patient, it would be obvious to one of ordinary skill in the art to insert a withdrawal needle in a surface peripheral vein near the skin surface of the patient with a reasonable expectation of success to provide reliable vascular access for a hemodialysis procedure.

With respect to **claim 59:** With regard to the limitation "the treatment is ultrafiltration", the method of Prosl meets all of the remaining limitations and is thus inherently capable of being practiced as an ultrafiltration treatment (see also Col. 3, lines 6-11).

With respect to **claim 54:** Prosl does not teach that the needle has a length of 35 cm to 40 cm. However since Prosl teaches that the needle is inserted into a vena cava 45 (Col. 2, lines 55-63), which is disclosed by applicant as a point of entry and requires a longer needle due to the vena cava's distal location with respect to the skin surface of the patient. Thus it would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the needle has a length of 35 cm to 40 cm with a reasonable expectation of success to ensure that the needle has sufficient length to perform the method of Prosl using the vena cava.

With respect to **claim 55:** The method of Prosl does not explicitly teach that the method further comprises after step (a) and before step (b) a determination that an amount of blood being withdrawn is insufficient for treating the blood because a blood flow rate through the needle is less than 40 milliliter per minute. However, since this determination is an arbitrary predetermined flow rate capable of being achieved by a patient and the method of Prosl, the method of Prosl is also capable of yielding a determination based upon the arbitrary flow rate. Thus it would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the method includes a determination that an amount of blood being withdrawn is insufficient for treating the blood because a blood flow rate through the needle is less than 40 milliliter per minute with a reasonable expectation of success to prevent undesired effects of the execution of the instant method.

With respect to **claim 56:** With regard to the limitation "the treatment is ultrafiltration", the method of Prosl meets all of the remaining limitations and is thus inherently capable of being practiced as an ultrafiltration treatment (see also Col. 3, lines 6-11) Prosl does not explicitly teach that the catheter is positioned in the vein for a period of at least four hours. However, it would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the catheter is positioned in the vein for a period of at least four hours with a reasonable expectation of success.

With respect to **claim 57:** Prosl teaches hemodialysis performed on the patient and thus teaches that the instant treatment is hemofiltration. (Col. 3, lines 10,11) Prosl does not explicitly teach that the catheter is positioned in the vein for a period of at least four hours. The time duration for positioning the catheter in the vein is considered herein to be a result-effective variable, as an increased time duration implies an increased volume of blood that is filtered, and thus an increased potential for proper treatment. It would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the catheter is positioned in the vein for a period of at least four hours with a reasonable expectation of success to process a greater amount of a patient's blood to impart a greater benefit from the filtration procedure. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

With respect to **claim 58:** Prosl teaches a dialysis session and thus teaches that the instant treatment is dialysis. (Col. 3, lines 6-9) Prosl does not explicitly teach that the instant catheter is positioned in the vein for a period of at least four hours. The time duration is considered herein

to be a result-effective variable, as an increased time duration implies an increased volume of blood that is filtered and treated, and thus an increased potential for proper treatment. It would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the catheter is positioned in the vein for a period of at least four hours with a reasonable expectation of success to process a greater amount of a patient's blood to impart a greater benefit from the dialysis procedure. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

With respect to **claim 60:** Prosl teaches inserting the withdrawal catheter 22 (part of the suction line) in the vascular system of the patient, but does not explicitly teach inserting the catheter in a surface peripheral vein 15 is in an arm of the patient. (Col. 16, lines 45-49) However, Prosl teaches other existing dialysis methods, specifically the arteriovenous fistula in which a catheter is inserted into a vein in a patient's arm. Since Prosl teaches that this alternate method of dialysis to the instant method is known, it would be obvious to one of ordinary skill in the art to modify the method of Prosl such that the withdrawal catheter 22 is inserted into a surface vein in a patient's arm with a reasonable expectation of success as an alternate means for creating the dialysis circuit. (Col. 2, lines 16-20)

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761